

DRAFT

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance Soy Protein Isolate

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Little environmental contamination is expected from manufacture, use, misuse or disposal. (Ostiguy) Eighty-one percent of soybean crop is genetically engineered.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601m.2]		X		Not listed as a list 1, 2, or 3 inert by EPA; several soybean oils are on List 3. TAP pg 7
5. Is there potential for detrimental chemical interaction with other materials used [§6518 m.1]		X		No potential for detrimental chemical interactions with organic farming system have been observed TAP pg 7
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		No potential for detrimental chemical interactions with organic farming system have been observed; readily metabolized by soil microorganisms into ammonium and nitrate ions. TAP pg 8
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		No detrimental effects are expected TAP 8
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		No adverse or toxic actions are expected TAP pg 8,9
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		Readily degradable organic material TAP pg 9
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		Soy contains phytoestrogens.Controversy exists concerning detrimental (estrogen mimic) and beneficial (cancer reduction & lowering of LDL/ increasing HDL) impacts but no health impacts are expected when used as a soil amendment. - Ostiguy
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600b.5]			X	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

DRAFT**Category 2. Is the Substance Essential for Organic Production?** Substance Soy Protein Isolate

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]			X	
2. Is there an organic substitute? [§205.600 b.1]			X	
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Other plant soil amendments are available; other fertilizers are manure, composted plant and animal materials TAP pgs 10,11
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
6. Are there any alternative substances? [§6518 m.6]	X			Other plant soil amendments are available; other fertilizers are manure, composted plant and animal materials TAP pg 11
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Soil fertility and crop nutrient management practices listed in 205.203; tillage/cultivation, green manure, crop rotation, cover cropping, TAP pg 11

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

DRAFT

Category 3. Is the substance compatible with organic production practices? Substance Soy Protein Isolate

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		Soy protein isolate has been petitioned for use as a fertilizer TAP pg 1; producers on organic farms “shall not use any fertilizers containing synthetic ingredients” OFPA 6508 (b)(1) or “use as a source of nitrogen, phosphorous, lime, potash, or any materials that are inconsistent with the applicable organic certification program” OFPA 6508 (b)(2)
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		Soy protein isolate has been petitioned for use as a fertilizer TAP pg 1; producers on organic farms “shall not use any fertilizers containing synthetic ingredients” OFPA 6508 (b)(1) or “use as a source of nitrogen, phosphorous, lime, potash, or any materials that are inconsistent with the applicable organic certification program” OFPA 6508 (b)(2)
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:				
a. copper and sulfur compounds		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?	X			“Soy protein isolate is being petitioned for use as a fertilizer” – a production aid

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB RECOMMENDED DECISION

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: May 2004

Substance: Soy Protein Isolate

A. Evaluation Criteria (Documentation attached; committee recommendation attached)

1. Impact on humans and environment
2. Availability criteria
3. Compatibility & consistency

Criteria Satisfied?

Yes ☐ No ☐ (see B below)

Yes ☐ No ☐ (see B below)

Yes ☐ No ☐ (see B below)

B. Substance fails criteria?

Criteria category: _____

Comments: _____

C. Proposed Annotation: _____

Basis for annotation: _____

To meet criteria above: _____ Criteria: _____

Other regulatory criteria: _____ Citation: _____

D. Final Board Action & Vote: Motion by: _____ Second: _____

Vote:

Yes: _____

No: _____

Abstain: _____

Agricultural		Nonagricultural		Crops	X
Synthetic		Not synthetic		Livestock	
Allowed ¹		Prohibited ²		Handling	
No restriction		Deferred ⁴		Rejected ³	

1—substance voted to be added as “allowed” on National List

Annotation: _____

2—substance to be added to “prohibited” paragraph of National List

Describe why a prohibited substance: _____

3—substance was rejected by vote for amending National List

Describe why material was rejected: _____

4—substance was recommended to be deferred

Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up. _____

E. Approved by NOSB Chair to transmit to NOP:

Dave Carter, NOSB Chair

Date

F. NOP Action: Include in FR to amend National List: ☐

Return to NOSB ☐ Reason: _____

Richard H. Mathews, Program Manager

Date

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>April 2004</u>	Substance: <u>Soy Protein Isolate</u>																																
Committee: Crops <input checked="" type="checkbox"/> Livestock <input type="checkbox"/> Handling <input type="checkbox"/>																																	
<p>A. Evaluation Criteria (Documentation attached; committee recommendation attached)</p> <table style="width: 100%;"><tr><td style="width: 50%;"></td><td style="width: 50%; text-align: right;">Criteria Satisfied?</td></tr><tr><td>1. Impact on humans and environment</td><td style="text-align: right;">Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)</td></tr><tr><td>2. Availability criteria</td><td style="text-align: right;">Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)</td></tr><tr><td>3. Compatibility & consistency</td><td style="text-align: right;">Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)</td></tr></table>			Criteria Satisfied?	1. Impact on humans and environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)	2. Availability criteria	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)	3. Compatibility & consistency	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (see B below)																								
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<p>B. Substance fails criteria?</p> <p>Criteria category: _____</p> <p>Comments: _____</p>	<p>C. Proposed Annotation: _____</p> <p>Basis for annotation: _____</p> <p>To meet criteria above: _____ Criteria: _____</p> <p>Other regulatory criteria: _____ Citation: _____</p>																																
<p>D. Recommended Committee Action & Vote: Motion by: _____</p> <p style="text-align: center;">Seconded: _____</p> <table style="width: 100%;"><tr><td style="width: 10%;"><u>Vote:</u></td><td style="width: 15%;"></td><td style="width: 15%;">Agricultural</td><td style="width: 15%;"></td><td style="width: 15%;">Nonagricultural</td><td style="width: 15%;"></td><td style="width: 15%;">Crops</td><td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td></tr><tr><td>Yes: _____</td><td></td><td>Synthetic</td><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Not synthetic</td><td></td><td>Livestock</td><td></td></tr><tr><td>No: _____</td><td></td><td>Allowed¹</td><td></td><td>Prohibited²</td><td></td><td>Handling</td><td></td></tr><tr><td>Abstain: _____</td><td></td><td>No restriction</td><td></td><td>Deferred⁴</td><td></td><td>Rejected³</td><td style="text-align: center;"><input checked="" type="checkbox"/></td></tr></table> <p style="text-align: center;">1—substance voted to be added as “allowed” on National List</p> <p>Annotation: _____</p> <p style="text-align: center;">2—substance to be added to “prohibited” paragraph of National List</p> <p>Describe why a prohibited substance: Soy protein isolate is a synthetic material. [Calcium or sodium is added to the protein to neutralize it.) Producers on organic farms “shall not use any fertilizers containing synthetic ingredients” OFPA 6508 (b)(1) or “use as a source of nitrogen, phosphorous, lime, potash, or any materials that are inconsistent with the applicable organic certification program” OFPA 6508 (b)(2)</p> <p style="text-align: center;">3—substance was rejected by vote for amending National List</p> <p>Describe why material was rejected: _____</p> <p style="text-align: center;">4—substance was recommended to be deferred</p> <p>Describe why deferred; if follow-up is needed. If follow-up needed, who will follow up _____</p>		<u>Vote:</u>		Agricultural		Nonagricultural		Crops	<input checked="" type="checkbox"/>	Yes: _____		Synthetic	<input checked="" type="checkbox"/>	Not synthetic		Livestock		No: _____		Allowed ¹		Prohibited ²		Handling		Abstain: _____		No restriction		Deferred ⁴		Rejected ³	<input checked="" type="checkbox"/>
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